GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:43
ANSWERED ON:27.07.2005
IRRATIONAL COMBINATIONS IN DRUGS
Muqueem Shri Mohammed;Shaheen Shri Abdul Rashid

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government is aware that various irrational combinations in drugs/pharmaceuticals are available and marketed in the country;

(b) if so, the details thereof;

(c) whether the Drug Controller General of India (DCGI) has expressed its inability to ban the irrational combinations;

(d) if so, the reasons therefor;

(e) the names of the irrational combinations and the companies which are marketing them under scrutiny by the DCGI; and

(f) the action taken/being taken by the Government in this regard?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a)to(f): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 43 FOR 27TH JULY, 2005 .....

Drugs in various dosage forms may consist of more than one active ingredient for various reasons like better patient compliance, synergistic or corrective action, to reduce the toxic or ill effect of a particular drug etc. and are generally marketed as Proprietary Medicines. Under the provisions of Drugs & Cosmetics Act and Rules made thereunder, the State Drug Licensing Authorities are empowered to grant licence for manufacture of drugs including combination formulations. The applicants at the time of applying for a licence for manufacture of such formulations are required to furnish to the Licensing Authority, the evidence and data justifying that the formulations contain the constituent ingredients in therapeutic/prophylatic quantities as determined in relation to the claims or conditions for which the medicines are recommended for use and the ingredients are stable and are in such quantities for which there is therapeutic justification.

In order to weed out irrational or harmful drugs, the Drugs and Cosmetics Act was amended in 1982, to empower Central Government to prohibit manufacture, sale and distribution of a drug if it is likely to involve any risk to human beings or animals or if any drug does not have therapeutic value claimed or contained ingredients in such quantities for which there is no therapeutic justification. In order to ensure adequate evaluation or rationality of such new drug formulations, the Drugs and Cosmetics Rules were amended in 2002 to make it mandatory for the State Licensing Authorites to ensure that the applicants for such new proprietary formulations, have the written approval from the Drugs Controller General (India) before granting the licence.

Drugs for which harmful effects are reported or for which therapeutic justification is considered inadequate in the context of current medical evidence, are examined by the Expert Committee under Drugs Technical Advisory Board (DTAB). It is a continuous process. So far, 76 drugs including various combination formulations have been prohibited for marketing in the country.

Drugs Controller General of India (DCGI) has not expressed inability to ban the irrational combinations. Applications for grant of NOC for manufacture such combination products received by the office of DCG(I) are examined as per prescribed norms in consultation with medical experts. Since, December 2004, 255 applications for NOC for manufacture of fixed dose combinations were received and out of which 38 have been rejected as these were considered irrational or having ingredients which have since been prohibited for manufacture and sale in the country.

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